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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/771,872	02/04/2004	Carina Horn	RDID 03020 US	3760	
7590 06/28/2005			EXAMINER		
Brent A. Harris			SNAY, JEFFREY R		
Roche Diagnos	tics Operations, Inc.		<u></u>		
9115 Hague Road, Bldg. D			ART UNIT	PAPER NUMBER	
Indianapolis, IN 46250			1743		
			DATE MAN CD 06/00/000	DATE MANY CID. OF 500 50005	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/771,872	HORN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Jeffrey R. Snay	1743				
The MAILING DATE of this communication Period for Reply	on appears on the cover sheet v	rith the correspondence address				
A SHORTENED STATUTORY PERIOD FOR IT THE MAILING DATE OF THIS COMMUNICAT - Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communicat - If the period for reply specified above is less than thirty (30) day. - If NO period for reply is specified above, the maximum statutory - Failure to reply within the set or extended period for reply will, b - Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	TION. CFR 1.136(a). In no event, however, may a tion. s, a reply within the statutory minimum of the period will apply and will expire SIX (6) MO y statute, cause the application to become A	reply be timely filed rty (30) days will be considered timely. NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed or	1 .					
	This action is non-final.					
Disposition of Claims						
4) Claim(s) 1-13 is/are pending in the application Papers	ithdrawn from consideration.					
Application Papers						
9)⊠ The specification is objected to by the Ex 10)⊠ The drawing(s) filed on 04 February 2004 Applicant may not request that any objection Replacement drawing sheet(s) including the 11)□ The oath or declaration is objected to by	f is/are: a)⊠ accepted or b)☐ to the drawing(s) be held in abeya correction is required if the drawin	nce. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received. 2. ☐ Certified copies of the priority documents have been received in Application No 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)	"□	O (DTO 440)				
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-93) Information Disclosure Statement(s) (PTO-1449 or PTO-Paper No(s)/Mail Date 07/19/04. 	48) Paper No	Summary (PTO-413) (s)/Mail Date Informal Patent Application (PTO-152)				

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DETAILED ACTION

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The presently claimed method for detecting an analyte, requiring steps which are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Specifically, claims 1-11 recite a method for detecting an analyte but positively recite only a single step of adding a reagent to the sample. The specification fails to enable how such single step would result in detection of an analyte.
- 3. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to teach how to make the claimed reagent.
- 4. The disclosure is objected to because of the following informalities: the term NBD-amine is not adequately defined.

Appropriate correction is required. No new matter should be entered.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The hand drawn molecular structure is illegible.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 12-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ghosh et al (1968).

See Ghosh et al at Table 1.

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 12. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoenes in view of Ghosh et al (1968).

Hoenes discloses an analytical method for determination of an analyte, e.g. glucose, by monitoring the optical change of a redox indicator. Suitable indicators include various benzfuroxanes. See column 5. The method of Hoenes differs from the instant claims in that the R1 and R2 substitutents appear to be nominally different. However, Hoenes teaches the general utility of benzfuroxane derivatives (lines 37-40). Ghosh et al disclose benzfuroxane derivatives that are the same as the compounds

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presently claimed. It would have been obvious to one of ordinary skill in the art to modify the method of Hoenes by selecting any known, and available compound within the disclosed genus of benzfuroxane derivatives, including those listed and enabled by Ghosh et al.

- 13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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